User Guide

Tight for life

Kegel 8®

www.Kegel8.co.uk

Warnings

* Do not insert lead wires into a mains power supply.
* Do not immerse unit into water or any other substance.
* Type BF equipment, Continuous Operation.
* Do not use the Kegel8® Tight & Tone unit in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
* If using rechargeable 9 Volt PP3 Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect the Kegel8® Tight & Tone directly to a battery charger or to any other mains powered equipment. We advise not to use Ni-Cad rechargeable batteries.
* Patient Probes and/or Electrodes are for ***single patient use only.***
* Keep out of reach of children.
* Do not use this stimulator on your facial area unless you are under strict guidance from a qualified Clinician.
* Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
* Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
* This unit must be used with the guidance of a Physiotherapist or Doctor.
* No modification of this equipment is allowed!

Symbols on the rear cabinet of Kegel8® Tight & Tone explained:

Caution (output)

Follow instructions for use

Type BF Equipment

Do not dispose in normal dustbin (see page 15 for the disposal instructions)

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What is STIM?

The Kegel8® Tight & Tone Pelvic Health Device is one of a new breed of modern Neuromuscular Stimulators (STIM) developed with the aim of achieving optimum pelvic health for women. Our principle aim was to design a product to give women the opportunity to tone and exercise their PC muscles, strengthen weak muscles and nerve fibres in a compact, easy to use device.

We also wanted the device to be straightforward and above all effective with the kind of medical credentials women demand.

Neuromuscular Stimulation has been used for many years to stimulate muscle and nerve fibres to treat a number of muscle and nerve related conditions. Over the last 30 years numerous clinical trials and papers have been written, you can view our Clinical References on page 15 of this users guide.

The Kegel8® Tight & Tone Pelvic Health Device is a dual channel device combining several treatment programmes into one unit. Neuromuscular Stimulation is increasingly understood by Therapists and Doctors. There is a better understanding of the mechanisms which exist between nerves and muscles that makes it possible to stimulate the neuromuscular system with precise electrical signals.

The Kegel8® Tight & Tone Pelvic Health Device offers precision giving full control of Pulse Widths, Rates, Ramp up times, Work / Rest cycles as well as alternating or synchronous application if two channels are being applied.

Customer Care

We welcome constructive comments regarding our equipment particularly those that might help us to improve existing features, add new ones or develop new products for the future.

Contra Indications & Precautions

Please read this Kegel8® Tight & Tone users guide before using this Stimulation device!

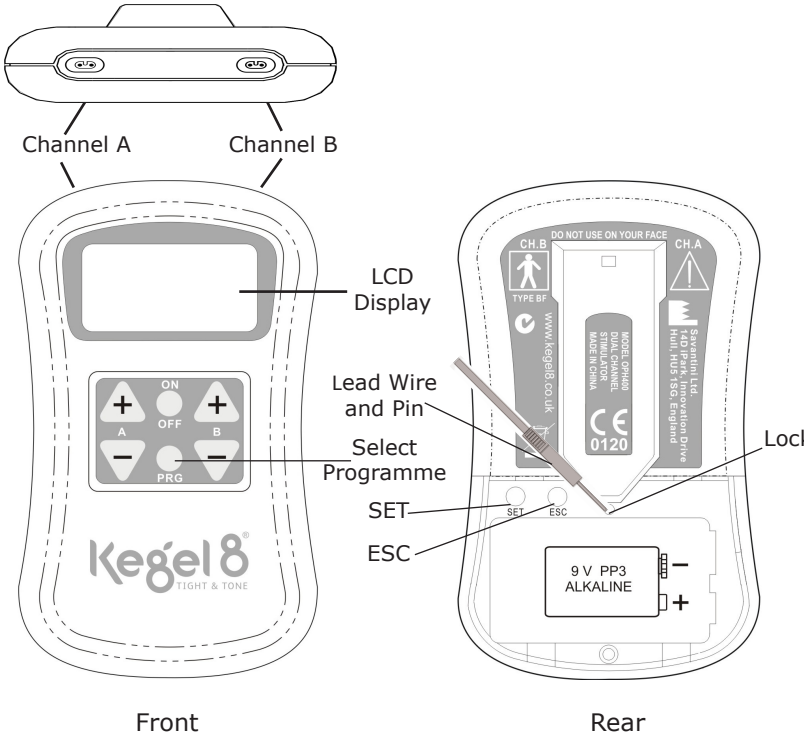
STIM should not be used:

* By patients fitted with a demand style cardiac pacemakers unless so advised by their Doctor.
* During pregnancy [unless medically advised].
* By patients with undiagnosed pain conditions.
* By patients with undiagnosed skin, vaginal or rectal conditions.
* With patients who have diminished mental capacity or physical competence who cannot handle the device properly.
* On anaesthetised or desensitised skin.
* When driving a vehicle or operating potentially dangerous equipment.
* Use the Kegel8® Tight & Tone only as directed.
* Do not immerse the unit in water or any other liquid
* Keep unit out of reach of children.
* If in doubt about the use of the Kegel8® Tight & Tone unit call your distributor for advice, Doctor, or Healthcare professional.
* Only use CE approved skin electrodes.
* Only use CE approved vaginal or rectal probes.

Do not place electrodes:

* Over carotid sinus nerves.
* Over larynx or trachea.
* Inside mouth.
* Over the area of the heart unless so advised by your Doctor.
* On your facial area unless under strict guidance from a qualified Clinician.

Description of the Kegel8® Pelvic Health Device & Functions



* **PRG button** - Selects the desired set programme from P01 - P09 or customised programme PC1 - PC3.

* **SET button** - Displays the menu and changes the parameters for Pulse Rate, Pulse Width, Time, Work, Rest, Ramp up time and ChA / ChB Synchronous or Alternating for custom programmes.

* **ESC button -** Stores customised programme and returns to the home position.

Lock Button

A "concealed" Lock button is included in the Kegel8® Tight & Tone Pelvic Health Device which allows the user to lock the device to their personal programme or to customise a personal programme.

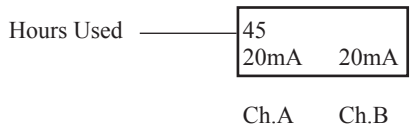
To Lock the Unit

1. Select the built in or customised programme required. In the case of a customised programme, make sure that the pulse width, frequency, time etc. are set-up correctly.
2. Remove the battery cover and, using a thin rod gently press on the lock button as shown in the diagram on page 6 until you hear a double beep. The unit is now "locked" and cannot be altered until "unlocked".

To Unlock the Unit

Remove the battery cover and press the concealed switch with a thin rod until a single beep is heard. Now the LCD will display the average mA used on each channel and the total hours the unit has been in use as shown in the diagram.

To return to normal "unlocked" operation, simply press ESC.



Quick Start Instructions

Lets Get Started

1. Insert the battery into the Kegel8® Tight & Tone control panel, slide off the cover, slot in the battery aligning the + and - accordingly. The red material strip goes under the battery and should be pulled to remove the battery to avoid damage to your Kegel8 controller. Slide the battery cover back on.

2. Take a control lead, with the black and red connectors at one end. Insert the white ended connector into the Kegel8 control unit, at the top left. This is called the A side, as shown on the unit's rear label. Push the lead tightly into the socket so it is fully connected.

3. Hold the probe at its base and insert it into the vagina, the base part remains outside the vagina. We recommend you use a lubricant to facilitate easy insertion, it also helps improve the level of conductivity of the stimulation to the muscles.

4. Plug the probe wire into the top left hand side of the controller, this is the A side used mainly for vaginal probes, and the B side can be used with an anal probe, please see online for more information or call our helpline.

5. Press the ON button on the Kegel8 control unit, the screen will illuminate. In the top right hand corner of the screen is displayed the programme setting. Click the PRG button (under the on/off button) to select your chosen programme - refer to page 10 to find the programme that's best for you, or call our helpline for more info.

6. To start the programme, press the + button on Channel A on the left hand side, you will see the mA change to 1, this will start your exercise programme, the programme icon will be replaced with a timer, this timer will count down through the routine and switch the unit off when your exercise is complete.

7. Please remember the higher the mA's the better the programme will be - more mA's = more eventual pelvic power. The mA's can reach a maximum of 99, however you must choose a level of mA's that is comfortable not painful. Increase the mA's using the + button on the A side, or decreased by using the – button on the B side.

8. At the end of the programme, your Kegel8 will automatically switch off. Remove the probe by its base; do not pull on the wires. Rinse the probe under running water to clean, ensuring the connectors do not get wet. Dry and store.

WARNING! Do not immerse the probe in boiling water, the probe can be sterilized in a mild solution such as Milton Sterilizing fluid if required, but we find a simple rinse in warm water is adequate.

Pre-set Kegel8 Tight&Tone Pelvic Health Programmes

Programme PO1 to PO9	Hz Rate	PW uS	Ramp up time in seconds	Work Time in seconds	Rest Time in seconds	Overall time in minutes
PAIN RELIEF P01	3	150	1	Cont		20
URGE P02	10	250	1	5	5	20
STRESS 1 P03	40	200	1	6	15	20
STRESS 2 P04	30	200	0.8	5	8	20
FREQ/URGE 1/NEW MOTHERS P05	10	200	1	5	5	20
FREQ/URGE 2 P06	10	200	1	Cont	0	15
LACK OF SENSATION P07	**Sequential**: 3Hz for 3 mins, 10Hz for 10 mins, 20Hz for 5 mins, 250uS, Ramp up time 0.8 secs, 30Hz for 4 mins, 40Hz for 3 mins 200uS Ramp up time 0.6 secs, Work Time 4 sec, Rest Time 4 sec					25
PELVIC FLOOR WORK OUT P08	**Sequential**: 20Hz for 3 mins, 3Hz for 5 mins, 10Hz for 15 mins, 20Hz for 15 mins, 250uS, Ramp up time 0.8 secs, 30Hz for 5 mins, 40Hz for 5 mins, 200uS, Ramp up time 0.6 secs 10Hz for 12 mins,250uS, Ramp up time 0.8 secs Work Time 4 sec, Rest Time 4 sec					60
BUILDING UP ENDURANCE P09	20	250	0.8	5	5	20
CUSTOMISED PC1, PC2, PC3						

Which Programme to select?

PO1 - Pain Relief
Vulvodynia is a chronic pain condition characterized by burning, stinging, irritation, and/or rawness in the female genital area this programme is designed to help. It also helps in cases where unknown pelvic pain has been diagnosed by a health care professional.

PO2 - Urge / Prolapse
Urge in this programme refers to a woman who does not have leakage problems, just the urge to pass urine. This programme is suitable for women suffering from bladder and vaginal prolapse. We can programme your K8 to help with anal prolapse, please telephone for more details.

PO3 - Stress 1
Stress incontinence is due to leakage of the bladder in particular when people jump up and down and when exercising or during lovemaking. This programme is set at a rate of 40Hz, the level favoured by UK physiotherapists.

PO4 - Stress 2
Stress incontinence is due to leakage of the bladder in particular when people jump up and down and when exercising or during lovemaking. This programme is set at a rate of 30Hz, the level favoured by Scandinavian physiotherapists.

PO5 - Frequency / Urge 1 / New Mothers
When a woman has the urge and frequency to actually pass urine several times during the day and night. This programme is recommended for new mothers who want to get back in shape after childbirth, start after your 6 week check up when you health care professional says it is OK to do so. After 12 weeks you can progress onto PO8 the thorough Pelvic Floor Workout, a couple of times a week.

PO6 - Frequency / Urge 2

When a woman has the urge and frequency to actually pass urine several times during the day and night. This programme is used primarily in Scandinavian countries. It offers continuous stimulation. They prefer continuous stimulation, whereas here in the UK we prefer a work/rest programme to allow the muscles to rest and recuperate.

PO7 - Lack of Sensation

In some women following childbirth, although they have good muscle control, they have a lack of sensation. This could mean nerve damage and this programme helps to recondition the muscles and to facilitate nerve sprouting to regain sensation.

PO8 - Pelvic Floor Workout

An excellent overall pelvic floor workout. Good for women entering or out of the menopause (but not suffering vaginal atrophy – see our FAQ's)

PO9 - Endurance

This programme is ideal if you feel your muscle tone is reasonable, and you can contract the muscle but you can't hold the contraction for long.

Custom Programme

Setting up the Customised Programme PC1, PC2 or PC3

Remove the battery cover where you will see two buttons SET and ESC, these buttons are used to set up your personal customised programme.

First press the ESC button to return to the home screen

1. Press the SET button and the Hz symbol will flash on/off, then press the + or – button on the front panel to adjust the Pulse Rate.

2. Press the SET button again and the µS symbol will flash on/off, then press the + or – button to adjust the Pulse Duration from 50 to 450 µS.

3. Press the SET button again and the Clock [Time] symbol will flash on/off, then press the Channel A +/- button to alter the hours and Channel B +/- button to adjust minutes. [Maximum time 1 hour 30 minutes].

4. Press the SET button again and the WRK [Work] symbol will flash on/off, then press the + or – button to adjust the work period from 2 –99 seconds.

5. Press the SET button again and the RST [Rest] symbol will flash on/off, then press the + or – button to adjust the rest period 2 – 99 seconds.

6. Press the SET button again and the RMP [Ramp up] symbol will flash on/off, then press the + or - button to adjust the ramp up period from 0.1 - 9.9 seconds.

7. Press the SET button again and ALT [Alternating] or SYN

   [Synchronous] symbol will flash on/off, then press the + or – button to select ALT or SYN.

After setting up the programme, press the ESC button to install and store the customised programme.

Repeat the above procedure to re-programme.

Care & Maintenance of your Kegel8 ® Tight & Tone

WARNING! Only medically approved accessories should be used!

Control Unit:

* Wipe the surface once a week with a damp cloth or antiseptic cleaner such us ***Kegel8 Klean***.
* Do not use alcohol based cleaning solutions.
* Control unit disposal: please return to us, see page 15.

Battery:

* To change the battery, open the battery door on the rear of the control unit by pressing down on the raised rib pattern just below the belt clip. Lift the battery out of the compartment. This is very easy and can be done by the user.
* Check periodically for any discharge from the battery.
* Remove battery completely from unit if not in use for any extended period of time (typically one week).
* Low battery indicator of 6.9 volts will show on LCD display. When flashing, change battery for a new one.
* Preferably use a GP Alkaline Pro 9v battery, these can be ordered separately.
* Battery disposal: please return to us, see page 15.

Lead Wires:

* The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
* Examine lead wires before each treatment for loose connections or damage.
* Avoid stretching and twisting the lead wires.
* Store the lead wires carefully after each use.
* Lead wires Disposal: please return to us, see page 15.

Vaginal / Rectal Probes:

* Check the connectors have not become separated from the probe.
* Before use the probe can be washed in warm soapy water, the probe may also be cleaned with our ***Kegel8 Klean*** antibacterial cleanser.
* Vaginal/Rectal Probe Disposal: please return to us and we will dispose for you in the environmentally friendly manner recommended by the WEEE Directive.

Caution: Static electricity may damage this product.

NOTE: Only our appointed distributors /importers are approved to undertake servicing.

Responsible Recycling Initiative

In compliance with Waste Electrical and Electronic Equipment (WEEE) Regulations 2006, we aim to reduce the amount of electrical waste being sent to landfill sites.

Electronic devices contain toxic materials which seep into the ground when dumped irresponsibly causing serious health and environmental problems. To recycle responsibly, all you need to do is return your device to us. We will:

- Carefully and correctly dispose of your old Kegel8®product
- Ensure as much of it is recycled as possible

Address:
WEEE Recycling
Savantini Limited
14D iPark, Innovation Drive
Kingston upon Hull
HU5 1SG
Great Britain

Applications

Why every woman should use the Kegel® Tight & Tone Pelvic Health Device

* The Kegel8® promotes continence.
* The Kegel8® increases and improves muscle strength.
* The Kegel8® maintains or improves range of movement.
* The Kegel8® increases and improves the blood supply to the muscle.
* The Kegel8® reduces pain.
* The Kegel8® strengthens the pubococcygeus (PC) muscles in order to prevent or reduce pelvic floor problems and to increase sexual satisfaction.
* The Kegel8® can be used to treat Vaginal and Uterine prolapses, depending on the severity of symptoms.
* The Kegel8® can strengthen the levator muscles, weakened by damage or lost nerve input from childbirth, especially in the case of c-sections, operations for hernia and hysterectomy.

Frequently Asked Questions

Q: I can't get the mA's past 6, 7 or 8

If you do not get an effective contact with the probe you will find that you cannot increase the mA's past level 6, 7 or 8. Initially we recommend you use the Kegel8 either lying down or sitting with your legs elevated. This will help you to get used to the Kegel8 sensation but also to stop the probe being displaced. It is important that the probe maintains contact with the muscles to contract and exercise them properly. If no contact, the mA's cannot go higher and cuts off as a safety feature. Conductivity is also improved by using a water based lubricant, suck us KE Gel.

Q: How far do I put the probe in?

The vaginal probe needs to be inserted just 2 inches (5.5 cm) this is the optimum level to stimulate the pelvic floor muscles.

Q: I have an IUD or Mirena Coil - can I use the Kegel8?

Yes. The Mirena is plastic so not problems there. An IUD contains copper which is unaffected by the Kegel8 and STIM so no problems there either.

Q: Can I use my Kegel8 when I have my period?

There are no problems with this, however if you are at the peak of your period and flow is heavy you may prefer not to. Many users have reported it helps with menstrual cramps too. Here in the office we tend to use it on lighter flow days. Rinse the probe in warm water and towel dry, the probe can be sterilized using a mild sterilizing solution if necessary, do not immerse the connectors at the ends of the leads in water, do not boil (it will cause the plastic to crack).

Q: I aim to have my mA's at 40, but on some programmes it drops to 30 - why is that?

While the programme goes through its preset routine the pulse width and pulse length varies, when the pulse rate and length increase the mA's drop so that the intensity does not take you by surprise, the mA's can again be increased. So if you feel a decrease in intensity increase the mA's back up to a comfortable level.

Q: Can I use it whilst pregnant?

Clinical guidelines advise against using any STIM machines vaginally during pregnancy.

Q: How soon after the birth of my baby can I start with my Kegel8® Tight & Tone?

Consult with your Midwife or Doctor. Generally women feel happy to start after a successful six week check-up.

Q: I have had pelvic surgery - how soon can I start using my Kegel8® Tight & Tone?

Consult with your Doctor or Consultant, every case is different, but the Kegel8 could help to speed recovery. Stress Incontinence, and prolapse is usually a sign of a weak pelvic floor, so if you have had an operation to help with either of these conditions you will still need to strengthen it. The Kegel8 is ideal, but check with your Doctor or physiotherapist.

Q: I find it painful inserting the probe.

Use a lubricant such as KE Gel, specially formulated for use with pelvic excercises. It helps with the conductivity - the better conductivity, the more the muscle will be exercised and the more mA's you'll be able to achieve.

If you are menopausal you could be suffering from vaginal atrophy, this causes vaginal dryness, thinning of the vaginal membrane and great discomfort. If the lubricant does not help, your Doctor can prescribe a course of oestrogen cream, use this for the recommended time (usually about one month), and then recommence using the Kegel8. Remember the pelvic floor needs to be exercised, do not be put off by vaginal atrophy, there are easy solutions for all women to overcome this painful condition.

Q: Why are there two channels?

Channel A (left hand side) is generally used for a vaginal probe, Channel B on the right hand side is generally used for an anal probe. If you have suffered from an anal prolapse please telephone us and we can help you with a customised programme for your condition, a selection of anal probes are also available online at www.Kegel8.co.uk

Q: How do I clean my probe?

Simply rinse the insertable part under the tap, keeping the wires dry at all times. Do not boil the probe. It can be sterilized using a mild sterilizing solution.

If you want to use the same probe vaginally and anally this is fine, but always clean the probe thoroughly.

Q: Why can I only feel stimulation on one side?

You do not have proper connectivity with the probe you need to adjust your position, ensuring the probe touches both sides of the vagina/ muscle wall. If your vagina has been stretched through childbirth and you are not feeling the probe on both sides, you need to sit with your legs tightly together, squeezing your pelvic floor as much as you can against the probe. Don't forget the lubricant to add greater conductivity.

Q: How long will the battery last?

If you use the Kegel8 daily, it should last about 3 months. You can get replacements from us or at your local supermarket - please choose a quality 9v battery that will not leak. You will know when your battery is low because a battery icon will flash on your Kegel8 screen.

Q: How long will my probe last?

With normal use your probe should last between 12 - 18 months. We recommend you replace it after this time to keep getting the maximum results from your Kegel8. We recommend you take care with the leads and wires of the probe don't bend them in two, or tie them up, this could cause wire damage and stop the probe working effectively. When inserting and removing the probe always hold the base of the probe, not the wires, especially when removing the probe. If you pull the wires instead of the probe base, you can damage the wires. We always offer a range of different probes for all uses, please check online or telephone us for more information.

Q: I can't find the answer to my question?

Give us a call or send an email, our customer service team is always here to help.

Specifications

STIM

1. Dual channel: individually isolated circuits.

2. Amplitude: 0 - 90 mA into 500 Ohm load; indication only. Actual mA will tend to be less than indicated due to electrode impedance: at 1000 Ohms load (Electrodes in poor condition) the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.

3. Type: Constant Current, maximum output voltage 180 Volts +10 / -30 Volts

4. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.

5. Selectable pulse width: 50 µS - 450 µS [2% accuracy].

6. Pulse Rate selection: in the continuous mode 2 Hz - 100 Hz [2% accuracy].

7. Time duration of the treatment selectable: 1 minute to 90 minutes.

8. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.

9. Open Electrode Detect: If an open circuit is detected at the output of channel A or B the output current will be reset at zero.

10. Ramp up time 0.3 - 9.9 seconds.

11. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on.

Physical dimensions: 108 x 62 x 23 mm.

Weight: 0.07KG without battery, 0.1KG with battery.

Environmental Conditions for use: +10 to +30 degrees Centigrade. 0-90% Humidity.

Environmental conditions for storage & transport: -10 to +50 degrees Centigrade. 0-90% Humidity.

Information regarding Electromagnetic compatibility and interference (EMC)

Kegel8® products are designed to produce very low levels of radio frequency (RF) emissions (interference), to be immune from effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge all when operating in a typical domestic and or clinical environment. They are certified to meet the international EMC standard EN60601-1-2

Table 201: Guidance and manufacturer's declaration - electromagnetic emissions

The Kegel8® product is intended for use in the electromagnetic environment specified below. The customer or the user of the Kegel8® product should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Kegel8® product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Kegel8® product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 202: Guidance and manufacturer declaration - electromagnetic immunity

The Kegel8® product is intended for use in the electromagnetic environment specified below. The customer or the user of the Kegel8® product should ensure that it is used in such an environment, and that precautions regarding that environment are heeded.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-2	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital ebvironment.

Table 204: Guidance and manufacturer's declaration - electromagnetic immunity

The Kegel8® product is intended for use in the electromagnetic environment specified below. The customer or the user of the Kegel8® product should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3V/m 80 MHz to 2, 5 GHz	3 Vrms 150 KHz to 80 MHz 3V/m 80 MHz to 2, 5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Kegel8® product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *d*=1.2√*P (150 KHz to 80 MHz);* *d*=1.2√*P (80 MHz to 800 MHz);* *d*=2.3√*P (800 MHz to 2.5 GHz);* *where P is the maximum output power rating of the transmitter in watts (W) acording to the transmitter manufacturer and d is the recommended separation distance in meters (m).* *Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* *(a) should be less than the compliance level in each frequency range;* *(b) interference may occur in the vicinity of equipment marked with the following symbol:*

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidlines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast connot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Kegel8® product is used exceeds the applicable RF compliance level above, the Kegel8® product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Kegel8 product.
(b) Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m.

Table 206: Recommended separation distances between portable and mobile RF communications equipment and Kegel8® product.

The Kegel8® product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Kegel8® product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment(transmitters) and the Kegel8® product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150k Hz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty

Savantini Ltd (Medical Dept) provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 2 years from the date of purchase [invoice date].

If Savantini Ltd is satisfied that the product/s is defective the purchaser may return this unit/s to Savantini Ltd (Medical Dept) or the appointed distributor for repair or replacement with a new unit.

All returns must first be authorised by Savantini Ltd (Medical Dept) in advance. The liability of Savantini Ltd (Medical Dept) under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear.

Any evidence of tampering will nullify this warranty.

Manufactured by:
Savantini Ltd., 14D iPark, Innovation Drive Hull, HU5 1SG, England

This product is manufactured in compliance with the European Union Medical Device Directive MDD93/42/EEC under the supervision of SGS, Notified Body number 0120.

CE 0120

Savantini Ltd., is certified by SGS to the following Quality Standards: ISO 9001:2008, ISO13485:2003.

Customer Service

Any queries should be addressed to:

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Clinical References

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Notes

Customer Service and Distribution:

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Manufactured by: Savantini Ltd. 14D Ipark, Innovation Drive,
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CE 0120

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